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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,189	01/23/2001	Stuart B. Levy	PKZ-021CP	1931

959 7590 08/29/2002

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BOSTON, MA 02109

EXAMINER
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BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/768,189

Applicant(s)

LEVY ET AL.

Examiner

Barbara P Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 12-14, 19-21, 28, 30, 33-51, 54, 55 and 58-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 6-8,10,11,15-18,22-27,29,31,32,52,53,56,57 and 71-77.

### **First Office Action on the Merits**

#### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, drawn to methods of controlling/treating *Cryptosporidium parvum* utilizing compounds of formula I wherein X is carbon (i.e., claims 1-10, 12-28 and 30-70 in part) in Paper No. 7 is acknowledged.
2. Claims 11, 29 and 71-77 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
3. Based on applicant elected species, 9-cyclopent-1-enyl-doxycycline, claims 6-8, 10, 15-18, 22-27, 31, 32, 52, 53, 56 and 57 stand withdrawn from further consideration as being drawn to a nonelected species.
4. Claims 1-5, 9, 12-14, 19-21, 28, 30, 33-51, 54, 55 and 58-70 have been examined to the extent they read on the elected species and doxycycline.

#### ***Information Disclosure Statement***

5. The information disclosure statement filed February 25, 2002 is noted, however, copies of the references are not in the case. The examiner is requesting copies of the non-patent references.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-5, 9, 12-14, 19, 30, 33-51, 54 and 59-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 77 and 81 of copending Application No. 09/823,884. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to treating a tetracycline responsive disease/cryptosporidium parvum related disorder utilizing overlapping tetracycline derivatives, including doxycycline. The difference between the two applications is in the scope of the tetracycline compounds recited. It is also noted that both "tetracycline responsive state" and "Cryptosporidium parvum related disorder" encompass the treatment of identical diseases including diarrhea.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim R jections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-5, 9, 12-14, 19-21, 28, 30, 33-39, 42-51, 54, 55 and 58-70 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim language creates confusion as to the claimed invention for the following reasons:

*W* Claims 1 and 45 recite "Cryptosporidium parvum related disorder". However, apart from the specific diseases set forth by the present specification (see page 14, lines 6-8 of the present specification), it is unclear what other disorders fall within the scope of the instant invention.

*W* Claims 2, 3, 46 and 47 recite "<sup>78-83</sup>**a prodrug moiety**" and claim 70 recites "paromomycin or **a derivatives thereof**". The present specification lacks definitions of said phrase and, thus, it is unclear what applicant intends. Therefore, the skilled artisan would be unable to determine the metes and bound of the claimed invention.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-5, 9, 12-14, 19, 30, 33-37 and 39-41 are rejected under 35

U.S.C. 102(a) as being anticipated by Armson et al.

Armson et al. teach the anticryptosporidial activity of doxycycline hydrochloride (see the entire article, especially Abstract). The method of use taught by the reference is encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

~~1-5, 9, 12-14, 19, 33-37, 39-41~~  
13. Claims 38, 42-51, 54 and 59-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armson et al.

Armson et al. teach the anticryptosporidial activity of doxycycline hydrochloride and the severity of *Cryptosporidium parvum*'s infection in immunocompromised and neonatal individuals (see the entire article, especially Abstract).

Claims 38 and 64 recite "wherein said human has undergone chemotherapy".

Claims 42-44 recite specific concentrations of tetracycline compounds that inhibit more than 70% of *Cryptosporidium parvum*.

Claim 45 recites treatment of *Cryptosporidium parvum* related disorder "in a mammal".

Claims 69 and 70 recite the addition of a supplementary anticryptosporidium *parvum* agent such as paromomycin.

However, the ordinary artisan in the art would (a) have the reasonable expectation that *Cryptosporidium parvum* growth in an individual would be inhibited by the prior art compounds irrespective of any prior treatment received by said individual and, thus, that the prior art compounds would inhibit the growth of said protozoa even in a human who has undergone chemotherapy; (b) be able to determine by routine experimentation the concentration(s) of the prior art compounds needed for inhibition of more than 70% of *Cryptosporidium parvum*; (c) have the reasonable expectation that the in vitro anticryptosporidial activity of the prior art compounds taught by Armson can be extrapolated to an in vivo system. Said extrapolation is done routinely in the medical art and (d) know that paromomycin is an anticryptosporidial agent (see page 231, col. 2, 32-35) and, thus, its combination with other compounds having similar effect to treat *Cryptosporidium parvum* infection would be prima facie obvious.

***Allowable Subject Matter***

14. Claims 20 and 21 are objected to as being dependent upon a rejected base claim.

Note: the claims are allowable to the extent they read on the elected species.




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***T I phon Inquiry***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
August 29, 2002